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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/971,791	11/17/97	EDWARDS	D MIR7513/7804
		HM42/1006	EXAMINER
PATREA L PABST ARNALL GOLDEN AND GREGORY 2800 ONE ATLANTIC CENTER 1201 WEST PEACHTREE STREET ATLANTA GA 30309-3450		SHELBYRNE	ART UNIT PAPER NUMBER
		1615	XG
		DATE MAILED:	10/06/98

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

#### OFFICE ACTION SUMMARY

Responsive to communication(s) filed on 11/17/97

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 1 - 38 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1 - 38 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.  
 received in Application No. (Series Code/Serial Number) 08/784421.  
 received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of Reference Cited, PTO-892  
 Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_  
 Interview Summary, PTO-413  
 Notice of Draftsperson's Patent Drawing Review, PTO-948  
 Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

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This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Receipt is acknowledged to the missing parts response filed 3-24-98; the letter filed 11-17-97 and the CFR filed 6/29/98.

***Claim Rejections - 35 U.S.C. § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5, 9 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Illum 4,904,479.

Illum teaches polystyrene microspheres of 5.25 micrometers diameter coated with poloxamer (note the abstract, columns 1-3, examples and claims). The intended use has no patentable significance in composition claims. In the absence of showing otherwise, it is deemed that Illum's microspheres have the claimed density.

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3. Claims 1, 4-6, and 9-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Yen (5,069,936).

Yen teaches protein microspheres containing a surfactant as polyoxamer (note columns 8, 11, 12, examples and claims). The intended use has no patentable significance in composition claims. In the absence of showing otherwise, it is deemed that Yen's microspheres have the claimed density.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claims 1-5, 9-15, 17-20, 24-30, and 32-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Baichwal (5,612,053).

Baichwal discloses powder formulations containing a therapeutic agent and a surfactant and a method of pulmonary delivery of drugs. The diameters of the particles taught by Baichwal encompass instant diameters (note the abstract, col. 2, line 40 through col. 7, line 42, col. 9, line 27 through col. 10, line 64 and claims). In the absence of showing otherwise, it is deemed that Illum's microspheres have the claimed density.

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***Claim Rejections - 35 U.S.C. § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baichwal cited above, further in view of applicants' statements of prior art.

As pointed out above, Baichwal does not specifically teach the tap density of the particles. Baichwal also does not teach that the particles be made of instant polyesters.

Applicants on pages 15-17 appear to state that the avoidance of macrophages by the aerodynamically light particles and their capability of the delivery of sustained release of the active agents in the lungs for a long time is known in the art. Applicants also state that the claimed biodegradable polyesters are also known in the art (page 10). To prepare Baichwal's particles with instant tap density would have been obvious to one of ordinary skill in the art since such particles would

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avoid macrophage uptake and deliver the active agent to lungs in a sustained fashion for a long time. The use of polymers such as polyesters not taught by Baichwal would have been obvious to an artisan since these are art known biodegradable polymers and one would expect similar delivery of drugs.

The examiner requests the copies of the references cited in the application.

***Claim Rejections - 35 U.S.C. § 103***

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masinde (International J. Of Pharmaceutics) of record in view of Illum (4,904,479), optionally in further combination with applicants' statements of prior art.

Masinde discloses polylactic acid (biodegradable and one of instant polymers) microspheres with a mean diameter of 12.1 micrometers (instant range: 5-30) and aerodynamic diameter of 2.1 micrometers (instant range 1-3 microns) (note the abstract and the Results & Discussion section). What is lacking in Masinde is the presence of surfactant.

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Illum as pointed out in the previous action, teaches micropheres of 5.25 micron diameter coated with the surfactant, poloxamer. According to Illum, the coating of the particles with a hydrophilic material will minimize the uptake of the blood components and a steric barrier to particle-cell interaction (note the abstract, col. 2, lines 1-7, examples and claims).

Applicants on pages 15-17 appear to state that the avoidance of macrophages by the aerodynamically light particles and their capability of the delivery of sustained release of the active agents in the lungs for a long time is known in the art. Applicants also state that the claimed biodegradable polyesters are also known in the art (page 10).

The use of a surfactant in the particles of Masinde would have been obvious to one of ordinary skill in the art since according to Illum, such a coating of the particles with a hydrophilic material will minimize the uptake of the blood components and a steric barrier to particle-cell interactions. Since Masinde's particles have the same polymer and same claimed diameters, it would be obvious to an artisan that they have the same tap densities. Assuming that they are different, to prepare Masinde's particles with instant tap density would have been

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obvious to one of ordinary skill in the art since such particles would avoid macrophage uptake and deliver the active agent to lungs in a sustained fashion for a long time as apparent from applicants' statement of prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kathryne E. Shelborne whose telephone number is (703) 308-3627. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

KES  
SHELBORNE; aco

October 2, 1998

T.K.P.  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
*ATLANTIC CITY*